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1636

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Khan et al.**Serial No.:** 10/028,075**Filed:** December 21, 2001**For:** GENE REGULATOR**Confirmation No.:** 1102**Examiner:** J. Dunston**Group Art Unit:** 1636**Attorney Docket No.:** 2183-5223US**CERTIFICATE OF MAILING**

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

September 25, 2006
Date
SignatureAubry Blackburn
Name (Type/Print)**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record. Copies of any cited foreign patents, publications, or pending unpublished U.S. applications are enclosed pursuant to 37 C.F.R. § 1.98(a)(2).

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
US - 2003/0148955	08-2003	Pluenneke
US - 4,427,660	01-1984	Schiffman et al.
US - 4,571,336	02-1986	Houck et al.

Serial No.: 10/028,075

US - 4,753,965	06-1988	Stemerick et al.
US - 5,002,961	03-1991	Dage et al.
US - 5,223,397	06-1993	Pouletty
US - 5,801,193	09-1998	Ojo-Amaize et al.
US - 5,942,494	08-1999	Ginsberg et al.
US - 5,972,924	10-1999	Keep et al.
US - 6,051,596	04-2000	Badger
US - 6,075,150	06-2000	Wang et al.
US - 6,235,281	05-2001	Stenzel et al.
US - 6,310,041	10-2001	Haddox et al.
US - 6,630,138	10-2003	Gerlitz et al.
US - 6,831,057	12-2004	Baldwin et al.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
WO 98/34631 A1	08-1998	Thomas Jefferson University
WO 2001/83554 A2	11-2001	Praecis Pharmaceuticals Incorporated et al.

Other Documents

ABRAHAM, E., "Coagulation Abnormalities in Acute Lung Injury and Sepsis," Am. J. Respir. Cell Mol. Biol., 2000, pp. 401-404, Vol. 22.

ADIB-CONQUY et al., "NF-kappaB Expression in Mononuclear Cells in Patients with Sepsis Resembles That Observed in Lipopolysaccharide Tolerance," Am. J. Respir. Crit. Care Med., 2000, pp. 1877-1883, Vol. 162.

ARIMA et al., "IL-2-Induced Growth of CD8+ T Cell Prolymphocytic Leukemia Cells Mediated by NF-kappaB Induction and IL-2 Receptor alpha Expression," Leukemia Research, 1998, pp. 265-273, Vol. 22, No. 3.

BAEGERLE et al., "Function and Activation of NF-kappaB in the Immune System," Annu. Rev. Immunol., 1994, pp. 141-179, Vol. 12.

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BODFISH et al., "Treating the Core Features of Autism: Are We There Yet?" Mental Retardation and Developmental Disabilities Research Reviews, 2004, pp. 318-326, Vol. 10.

BROWN et al., "Two Forms of NF-kappaB1 (p105/p50) in Murine Macrophages: Differential Regulation by Lipopolysaccharide, Interleukin-2, and Interferon-gamma," Journal of Interferon and Cytokine Research, 1997, pp. 295-306, Vol. 17.

EMMEL et al., "Cyclosporin A Specifically Inhibits Function of Nuclear Proteins Involved in T Cell Activation," Science, 22 December 1989, pp. 1617-1620, Vol. 246.

EPINAT et al., "Diverse agents act at multiple levels to inhibit the Rel/NF-kappaB signal transduction pathway," Oncogene, 1999, pp. 6896-6909, Vol. 18.

FAUST et al., "Disseminated intravascular coagulation and purpura fulminans secondary to infection," Bailliere's Clinical Haematology, 2000, 179-197, Vol. 13. No. 2.

JIMENEZ-GARZA et al., "Early Effects of Modulating Nuclear factor-kappaB Activation on Traumatic Spinal Cord Injury in Rats," Ann. N.Y Acad. Sci., 2005, pp. 148-150, Vol. 1053.

KIDD et al., "Autism, An Extreme Challenge to Integrative Medicine. Part II: Medical Management," Alternative Medicine Review, 2002, pp. 472-499, Vol. 7, No. 6.

KRONFOL et al., "Cytokines and the Brain: Implications for Clinical Psychiatry," Am. J. Psychiatry, May 2000, pp. 683-694, Vol. 157, No. 5.

LI et al., "NF-kappaB Regulation in the Immune System," Nature Reviews/Immunology, October 2002, pp. 725-734, Vol. 2.

MALEK-AHMADI, P., "Role of Cytokines in Psychopathology: Therapeutic Implications," Drug News Prospects, June 1998, pp. 271-276, Vol. 11, No. 5.

MCKEAN et al., "Rodent Models of Global Cerebral Ischemia: A Comparison of Two-Vessel Occlusion and Four-Vessel Occlusion," Gen. Pharmac., 1998, pp. 431-434, Vol. 30, No. 4.

MCDONALD et al., "Interleukin-15 (IL-15) Induces NF-kappaB Activation and IL-8 Production in Human Neutrophils," Blood, 15 December 1998, pp. 4828-4835, Vol. 92, No. 12.

NEELY et al., "Then and now: Studies using a burned mouse model reflect trends in burn research over the past 25 years," Burns, 1999, pp. 603-609, Vol. 25.

SMITH et al., "Recent developments in drug therapy for multiple sclerosis," Multiple Sclerosis, 1999, pp. 110-120, Vol. 5.

TRAYSTMAN, R., "Animal Models of Focal and Global Cerebral Ischemia," ILAR Journal, 2003, pp. 85-95, Vol. 44, No. 2.

WEINBERGER et al., "Mechanisms Mediating the Biologic Activity of Synthetic Proline, Glycine, and Hydroxyproline Polypeptides in Human Neutrophils," Mediators of Inflammation, 2005, pp. 31-38, Vol. 1.

YANG et al., "Increased cortical nuclear factor kappaB (NF-kappaB) DNA binding activity after traumatic brain injury in rats," Neuroscience Letters, 1995, pp. 101-104, Vol. 197.

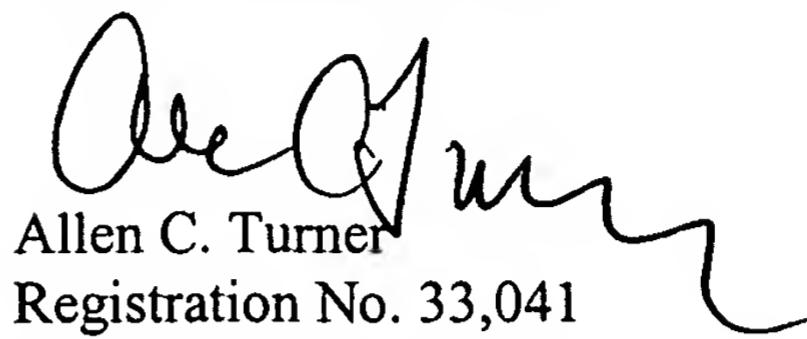
In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, Applicants hereby identify the following listed copending applications naming a common inventor(s):

Attorney Docket No.: 2183-7350.1US
Serial No.: 11/481,423
Filed: 7/5/2006
Title: TREATMENT FOR TUMORS

This Supplemental Information Disclosure Statement is believed to be filed before the mailing date of the first Office Action on the merits subsequent to the filing of an RCE in the above-identified application.

Serial No.: 10/028,075

Respectfully submitted,



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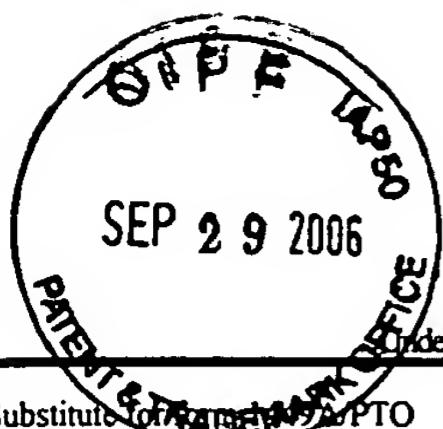
Date: September 25, 2006

ACT/alb

Enclosures: Form PTO/SB/08

Cited Non-U.S. Patent Documents

Document in ProLaw



SEP 29 2006

PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substituted for ~~APRIL 19, 1949~~ APTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheer

of

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Attorney Docket Number

Complete if Known

Application Number	10/028,075
Filing Date	December 21, 2001
First Named Inventor	Khan et al.
Group Art Unit	1636
Examiner Name	J. Dunston
Attorney Docket Number	2183-5223US

Attorney Docket Number 2183-5223US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US-2003/0148955	08-2003	Pluenneke	
		US- 4,427,660	01-1984	Schiffman et al.	
		US- 4,571,336	02-1986	Houck et al.	
		US- 4,753,965	06-1988	Stemerick et al.	
		US- 5,002,961	03-1991	Dage et al.	
		US- 5,223,397	06-1993	Pouletty	
		US- 5,801,193	09-1998	Ojo-Amaize et al.	
		US- 5,942,494	08-1999	Ginsberg et al.	
		US- 5,972,924	10-1999	Keep et al.	
		US- 6,051,596	04-2000	Badger	
		US- 6,075,150	06-2000	Wang et al.	
		US- 6,235,281	05-2001	Stenzel et al.	
		US- 6,310,041	10-2001	Haddox et al.	
		US- 6,630,138	10-2003	Gerlitz et al.	
		US- 6,831,057	12-2004	Baldwin et al.	
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO				<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/028,075
<i>(use as many sheets as necessary)</i>				Filing Date	December 21, 2001
				First Named Inventor	Khan et al.
				Group Art Unit	1636
				Examiner Name	J. Dunston
Sheet	2	of	3	Attorney Docket Number	2183-5223US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
		ABRAHAM, E., "Coagulation Abnormalities in Acute Lung Injury and Sepsis," Am. J. Respir. Cell Mol. Biol., 2000, pp. 401-404, Vol. 22.		T ²
		ADIB-CONQUY et al., "NF-kappaB Expression in Mononuclear Cells in Patients with Sepsis Resembles That Observed in Lipopolysaccharide Tolerance," Am. J. Respir. Crit. Care Med., 2000, pp. 1877-1883, Vol. 162.		
		ARIMA et al., "IL-2-Induced Growth of CD8+ T Cell Prolymphocytic Leukemia Cells Mediated by NF-kappaB Induction and IL-2 Receptor alpha Expression," Leukemia Research, 1998, pp. 265-273, Vol. 22, No. 3.		
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		BETHEA et al., "Traumatic Spinal Cord Injury Induces Nuclear Factor-kappaB Activation," The Journal of Neuroscience, 1 May 1998, pp. 3251-3260, Vol. 18, No. 9.		
		BODFISH et al., "Treating the Core Features of Autism: Are We There Yet?" Mental Retardation and Developmental Disabilities Research Reviews, 2004, pp. 318-326, Vol. 10.		
		BROWN et al., "Two Forms of NF-kappaB1 (p105/p50) in Murine Macrophages: Differential Regulation by Lipopolysaccharide, Interleukin-2, and Interferon-gamma," Journal of Interferon and Cytokine Research, 1997, pp. 295-306, Vol. 17.		
		EMMEL et al., "Cyclosporin A Specifically Inhibits Function of Nuclear Proteins Involved in T Cell Activation," Science, 22 December 1989, pp. 1617-1620, Vol. 246.		
		EPINAT et al., "Diverse agents act at multiple levels to inhibit the Rel/NF-kappaB signal transduction pathway," Oncogene, 1999, pp. 6896-6909, Vol. 18.		
		FAUST et al., "Disseminated intravascular coagulation and purpura fulminans secondary to infection," Bailliere's Clinical Haematology, 2000, 179-197, Vol. 13, No. 2.		
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STATEMENT BY APPLICANT

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Sheet

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of

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Attorney Docket Number	2183-5223US

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials *	Cite No. ¹	
		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
		KIDD et al., "Autism, An Extreme Challenge to Integrative Medicine. Part II: Medical Management," Alternative Medicine Review, 2002, pp. 472-499, Vol. 7, No. 6.
		KRONFOL et al., "Cytokines and the Brain: Implications for Clinical Psychiatry," Am. J. Psychiatry, May 2000, pp. 683-694, Vol. 157, No. 5.
		LI et al., "NF-kappaB Regulation in the Immune System," Nature Reviews/Immunology, October 2002, pp. 725-734, Vol. 2.
		MALEK-AHMADI, P., "Role of Cytokines in Psychopathology: Therapeutic Implications," Drug News Prospects, June 1998, pp. 271-276, Vol. 11, No. 5.
		MCBEAN et al., "Rodent Models of Global Cerebral Ischemia: A Comparison of Two-Vessel Occlusion and Four-Vessel Occlusion," Gen. Pharmac., 1998, pp. 431-434, Vol. 30, No. 4.
		MCDONALD et al., "Interleukin-15 (IL-15) Induces NF-kappaB Activation and IL-8 Production in Human Neutrophils," Blood, 15 December 1998, pp. 4828-4835, Vol. 92, No. 12.
		NEELY et al., "Then and now: Studies using a burned mouse model reflect trends in burn research over the past 25 years," Burns, 1999, pp. 603-609, Vol. 25.
		SMITH et al., "Recent developments in drug therapy for multiple sclerosis," Multiple Sclerosis, 1999, pp. 110-120, Vol. 5.
		TRAYSTMAN, R., "Animal Models of Focal and Global Cerebral Ischemia," ILAR Journal, 2003, pp. 85-95, Vol. 44, No. 2.
		WEINBERGER et al., "Mechanisms Mediating the Biologic Activity of Synthetic Proline, Glycine, and Hydroxyproline Polypeptides in Human Neutrophils," Mediators of Inflammation, 2005, pp. 31-38, Vol. 1.
		YANG et al., "Increased cortical nuclear factor kappaB (NF-kappaB) DNA binding activity after traumatic brain injury in rats," Neuroscience Letters, 1995, pp. 101-104, Vol. 197.

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